

Montana Health Care Database Advisory Council

Report of Recommendations to the
Commissioner of Securities and Insurance
As Per Montana Legislative Study Bill HB573

August 2012

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EXECUTIVE SUMMARY:

Background

Montanans spend about \$7 billion annually on health care, which represents about 18% of our annual state gross domestic product. Costs for health care service spiral upward every year at a rate higher than general inflation, and higher than growth in both our domestic product and wages. Everyone feels it – health care takes a greater and greater percentage of what we have to spend, and leaves less for everything else. On top of rising costs, experts have estimated that around 30% of the total dollars spent on health care do not improve the health of patients.¹⁰⁾

Health care consumes approximately 23% of our state budget, and our state health care expenditures increase at a much higher rate - around 8% - than either inflation or wage growth. The state health programs that comprise the bulk of state health expenditures (Medicaid, Healthy Montana Kids, and the state employee health plan) are expected to cost \$1.1 to \$1.2 billion in each year of the current biennium. While the growth rates in state health costs are similar to those in the commercial health care market, they are clearly unsustainable in the long run, both in our state budget and in the broader economy.

Across the country, states are struggling to gain a better understanding of their health care systems and to manage both the cost and quality of those systems. But health care systems are not transparent. Our historical third party payment structure creates disconnects between patients and costs, price and quality, and between decision makers and the information needed to make better health choices.

If we are to do better at managing our health care systems, and using our health care dollars more effectively, we must have a comprehensive data set of health costs and expenditures. It has been said many times: you can't manage what you can't measure. Also, in order for market systems to be successful, information concerning health care cost, quality, and treatment effectiveness needs to be widely available to the public.

All Payer Claims Databases

All payer claims databases (APCDs) are a rapidly emerging and powerful tool in helping states to create transparency regarding health care pricing, quality, and utilization. Fourteen states have already implemented APCDs, including our neighbors in Colorado, Utah and Oregon; and

many more states are considering their implementation. The National Governor's Association has called for their development in all 50 states.

An APCD is a database that includes data from medical, eligibility, provider, pharmacy, and dental files; from both private and public payers of medical insurance claims. Payers contributing data typically include insurance carriers, Medicare and Medicaid, third party administrators, health plans, and pharmacy benefit managers.

APCDs provide a variety of benefits in managing health care system costs and promoting value. They provide the data necessary to evaluate critical issues such as regional variations in utilization, quality and cost. They can be used to study the impact of reimbursement methodologies and public health interventions. They can provide the data to do meaningful comparative effectiveness research. They can also be a key source to inform and support policy decisions, and drive health care system improvement.

Who Uses APCDs, and in What Ways?

Policy makers can use the database to identify areas of disparity in costs and outcomes, identify high performing areas and best practices to spur improvements in low performing areas, to understand and address utilization issues, to compare public system reimbursement (Medicaid, Medicare) to commercial payments, to identify regional variations in care, detect and reduce fraud in publicly funded health systems, and much more.

Medical providers are able to review their costs and outcomes across their entire range of patients, and not just those covered by one plan. They will be able to compare their results and costs to their peers across the state, develop best practices, and provide improved services to the public at a lower cost.

Insurers and health plans are better able to identify variability in costs and outcomes, detect fraud and abuse, and can use APCD data to assist with both contract and benefit design that identifies and rewards high value providers.

Businesses purchasing insurance are able to identify cost and quality indicators for the providers in their plans' networks, helping them to evaluate their health care expenditures,

compare their experience to others, and choose the best plans and benefits for their business needs.

Consumers are able to compare costs, quality measures and benefits among and across providers and make more informed choices about providers and health plans. The APCD will assist in creating the transparency necessary to develop a health care marketplace.

Researchers, such as those at our universities, are able to use APCDs for a wide range of public health and health system research projects.

These are but a few of the wide and varied uses of the consolidated data that can only be provided through a statewide data repository.

HB 573: To Study Creation of a Montana APCD

The 2011 legislature passed HB 573, an act to study the creation of an APCD in Montana. The study was assigned to the Commissioner of Securities and Insurance, and called for the formation of an advisory council to “review the costs, benefits, and procedural and technical requirements necessary to design, implement, and maintain a statewide all-payer all claims database for health care.”

Commissioner Lindeen appointed a council comprised of key stakeholders including insurers, medical providers, consumer representatives, business representatives, and state policy makers. The council has been meeting monthly since December of 2011, and has studied the implementation of APCDs in other states, along with the costs and benefits of implementing an APCD in Montana.

The advisory council has adopted a mission statement for a Montana APCD. It states: “the goal of the Montana Health Care Database is to provide a comprehensive, accurate, and transparent picture of our health care system. It will be a resource for improving health care system performance and value, and will create the ability for policy makers, consumers, insurers, providers and employers to make more informed and cost effective health care choices.”

The council has also adopted a set of governing principles, and technical scope and attributes statements that will guide the development of the database. These principles include the

confidentiality of and protection of health information, the adoption of national standards for datasets where possible, the recognition of the need for a phased-in approach to data collection, and a governance structure for the database.

This Report

The bulk of this report summarizes the work and recommendations of the APCD Advisory Council. It includes background information on claims data and analytical tools; clinical data and uses; research implications; value to the insurance marketplace; confidentiality of data; and the guiding principles for the APCD adopted by the Council.

HEALTH CARE CLAIMS PAYMENT DATA:

A truly comprehensive APCD, designed to serve the needs of a variety of potential users, will require several diverse data sets. However, the initial focus of a successful APCD needs to concentrate on claims payment information. The advantages of accessibility, standardization and clinical information which are contained in claims data are why all current state-initiated APCDs start by collecting claims payment data.

Major medical and pharmacy claim data are the backbone for APCD data aggregation and analytics. They provide transaction information for professional, institutional, and pharmacy claims between providers and claims processors, including third party administrators and insurance carriers (payers). Almost all health services provided in the United States create a financial claim for payment, virtually assuring that a record for that specific health-related patient encounter is created.

Successful APCDs combine data from all payers, providing invaluable statewide information on cost, quality, and utilization patterns. They also provide sufficient numbers for each and every provider to make meaningful comparisons. Many APCD data strategies also include the collection of claim-based information on insurance plans' enrollment; including membership, demographic statistics and benefit information.

This combination of data allows for research on both access and barriers to care, as well as numerous other health care measures. When these data are made publicly available, consumers and purchasers have the tools they need to compare prices and quality as they

make health care decisions. APCDs are proving to be powerful tools for all stakeholders in states where they are being used, filling in longstanding gaps in health care information.

As with all data sets, there are limitations to APCD data, however, capturing this information from patient care encounters creates an accessible and powerful information source. Each coverage type has its own set of claims data, including **Medical, Pharmacy, Dental**, and **Vision**, and each vary by the level of detail of the data that is submitted, processed and stored.

Medical Claims Data – Almost every health encounter creates a claim for payment, and evolving versions of standardized medical coding have created data that is even more comprehensive and useful than previously created medical claims data. New code formats have the ability to reflect greater detail within the code, more specific information about the diagnosis, and provide more flexibility for new technologies and diagnoses.

Pharmacy Claims Data - Pharmacy claims data contains the National Drug Code (NDC) which is a drug product classification system. The NDC was first used as part of a Medicare outpatient drug reimbursement plan. Today the NDC has spread to many other sectors of the health care industry including hospitals, managed care organizations, pharmaceutical manufacturers, and Medicaid. Its uses include clinical patient profile screening, inventory control, and drug claims processes.

Dental Claims Data - Dental claims data contains less clinical information than vision or medical claims, nevertheless the value of that information is still remarkable and has been well described.¹⁾ Minimum benefit packages covered by health plans may soon include certain oral health care procedures, therefore increasing the amount of dental claims data available. This would also put more emphasis on generating, transmitting and storing additional clinical information from dental claims.

Vision Claims Data - Vision claims data contain valuable diagnostic, utilization, and cost information. However because vision claims may be paid differently from other types of claims, and not all benefit plans cover vision services, they are rarely aggregated. Additionally recent clinical studies find that many chronic diseases are first identified through a common eye exam,

creating a further reason for including vision claims data in the claims aggregation process.

Claims Data Summarized: Many APCDs have recognized the value and shortcomings of collecting claims data. Therefore, planning a phased approach to aggregating all available information into one database is a universal strategy. The common availability of claims data, and the less available nature of other data (such as clinical), has prompted APCDs to begin with aggregating claims data.

CLINICAL DATA:

Clinical data, in its broadest sense, includes all information derived from a provider's medical interaction with a patient: history - including medications, allergies, problem list; physical examination findings; laboratory; and all other diagnostic testing. This information comprises the provider's patient record. In the past all of this information was on paper. It is now in the process of moving almost entirely to an electronic format, making that information available for electronic exchange, aggregation and analysis. Electronic exchange and use of clinical data is subject to the strictest security and privacy controls.

An APCD traditionally includes only administrative (claims) data gathered from health care payers and other sources. A comprehensive review of administrative data systems noted that "The principle disadvantage of administrative data is that one is limited to the data elements that were introduced, almost always for a totally different purpose. This has become particularly pertinent as hospitals and other providers are being compared based upon the 'outcomes' of care."²⁾

A 2006 Agency for Healthcare Research and Quality (AHRQ) report "Adding Clinical Data Elements to Administrative Data for Hospital-Level Reporting" concluded that "The results of this study demonstrate that selected clinical laboratory data elements added to administrative data can improve the accuracy of the risk adjustment models for comparing hospital mortality rates."³⁾

In 2008 AHRQ stated that "Providing clinical detail within administrative data records will enhance the ability to report publicly on the quality and cost of care, as well as improve the accuracy, transparency, research capacity, and value of administrative data."⁴⁾

A 2009 AHRQ Results Final Report, *Adding Clinical Data to Statewide Administrative Data: Pilot Project*, concluded that "The findings of this pilot project demonstrate that clinical data, when combined with the 'Present on Admission' indicator and administrative inpatient data, can be used to improve the risk adjustments models to better predict the risk of patient mortality" ⁵⁾

In addition to the AHRQ work, much additional research in many different settings has specifically demonstrated the value of combining clinical data with administrative data. ⁶⁾

Despite much strong evidence in favor of combining clinical and administrative data, such integration remains uncommon outside of specifically funded research settings. Of the statewide APCDs reviewed by the APCD Advisory Council none currently include clinical data. The final report from The Agency for Health Care Administration (AHCA) - Florida Center for Health Information and Policy Analysis explains part of the reason, in detailing its participation in the 2009 AHRQ Project: "Since laboratory test results are not currently collected in administrative data, there will be considerable effort and cost associated with any mandate to report laboratory test results." ⁷⁾

Although the Florida comment is specific to laboratory results as an example of clinical data, the effort and cost required to include broader clinical data with administrative data in an Integrated Data Repository (IDR) would be expected to be even greater. The reason is that all of the different clinical data sources would have to be independently interfaced with the IDR.

Another reason APCDs are not collecting clinical data is the high percentage that is not currently available in an electronic format. A 2011 National Center for Health Statistics brief reported that only 38.3 percent of office-based physicians in Montana reported having a system that meets the federal criteria for a basic system. ⁸⁾ Adoption of Electronic Health Record (EHR) systems is increasing, but this fact shows why incorporating clinical data into a Montana APCD might be reserved for a future phase.

The advent of statewide Health Information Exchanges (HIE), with the HIE serving to aggregate statewide clinical data, is eliminating this cost barrier. A December 2010 AHRQ report, *Future Directions for the National Healthcare Quality and Disparities Reports*, stated that "Although surveys and administrative databases are enormously valuable, measuring outcomes often requires detailed clinical data collected at the point of care ... there is potential for data linkages between health information exchanges (HIEs) and APCD databases." ⁹⁾

This potential for clinical HIE data to support administrative data is currently recognized in Montana. The Montana Blue Cross Blue Shield Patient Centered Medical Home infrastructure will combine clinical data with administrative data; as will the developing Rocky Mountain Health Network and Employee Benefit Management Services partnership, to develop an Accountable Health Network. Two other organizations currently collecting and analyzing clinical data are HealthShare Montana and the Montana Association of Health Care Purchasers.

Payer and health care organizations are increasingly being held to higher levels of accountability for health care quality and costs. Each possesses data with powerful potential to assist one another in accomplishing shared goals. A combined view of clinical data from health care organizations and administrative data from payers has the potential to generate a far more comprehensive view of health care quality, patient outcomes and costs than can either set of data independently. Combining clinical and administrative information has synergistic potential to exponentially increase the power contained within these large pools of data. Ultimately, the public will benefit as the path to a more affordable and sustainable health care system is illuminated, by the sophisticated use of combined clinical and administrative data.

The APCD Advisory Council has broadened the APCD concept by suggesting that Montana's effort be called the "Montana Health Care Database". What would this integration of clinical and administrative data actually mean for Montana users, which includes: patients, providers, payers and researchers? An Integrated Data Repository will allow various disparate data sources (i.e. clinical data, administrative data, pharmacy data, lab data, optometry office data, dental office data, census data, etc.) from across the state to be consolidated. The aggregated data will support research and analysis that can be used to pursue and optimize the triple aim of improving patient health care, improving population health and reducing per capita cost.

RESEARCH OPPORTUNITIES:

Over the last 30 years personal health care spending in the state of Montana has increased at an average annual rate of 8.4 percent, above the national average annual growth rate of 8.1 percent. At this rate of growth, spending on health care by Montanans is doubling every eight years, while per capita personal incomes are doubling only every 16 years. For a state where

personal health care spending accounts for 18 percent of the state's entire gross domestic product, understanding what is behind this rate of growth is imperative.

While we may know how fast health care spending is increasing, we know very little about why it is increasing. These gaps in knowledge limit our ability to identify and address the factors behind rising health care costs. Data on Montana's health care delivery system is needed to provide robust information about the cost and performance of Montana's health care delivery system. APCDs provide an opportunity to develop health care reforms that address spiraling health care costs in Montana, while expanding access and improving public health.

APCDs nationally have shown that aggregating health care data provides a reliable data source for multiple stakeholders to use, to examine variations in efficiency, quality, safety and cost. These results can be shared with providers, purchasers, and consumers to support an environment to improve health care quality and efficiency. With price transparency, consumers can make more informed value-based choices, an option not available today.

Many APCD's have two types of data sets. One is a fully identified, HIPAA compliant, highly restricted and limited access administrative data set. This is used to support advanced research and payer/provider only access. More common however are payer blinded, patient de-identified and cost standardized data sets that are fairly unrestricted and available for public use. These data sets are used in a wide variety of applications, but all support policy or practice changes that improve quality, cost and access.

HOW OTHER STATES USE APCDs:

APCDs are used in many different ways by states. One of the first multiple-state uses was an evaluation conducted for Maine, New Hampshire, and Vermont. For a set population, utilization of services and insurance claims payments were compared between states, as well as among different areas within the states. Wide variations in the rate of health care utilization were found, as well as variations in claims payments per member per month. Also, variations in potentially avoidable emergency department visits were used to identify possible shortages in the availability of primary care physicians.

Vermont used its APCD to support enhanced insurance rate review activities. Massachusetts used theirs to identify the factors that explain why health care costs were increasing faster than general inflation. These cost trends were examined to inform policy discussions on care coordination, payment reform, and insurance product design. The study found, for instance, that there was wide variation in payments made by health insurers that was not explained by differences in the quality of care.

The most exhaustive studies to date come from New Hampshire, one of the first states to have an APCD. Their numerous studies include: the role of caesarian sections as an insurance cost driver, a thorough examination of the ambulance market, the educational value of price transparency efforts, relative costs between New Hampshire hospitals, and the relationship between increasing costs to consumers and increases in payments to providers.

Wisconsin used data from an APCD to study health care use by area, according to the first three digits of the zip code. New York studied outpatient care patterns and potentially avoidable emergency department visits. Massachusetts studied the relationship between provider costs and payer premium rates, the impact of payment and delivery system reforms, and the factors contributing to the rapid increase in health care costs.

As more states develop APCDs, the knowledge base and comparative statistics will increase. This will help to identify variation and best practices in transparency, health care reform efforts, and state and local health care policy.

MARKET-BASED CONSIDERATIONS:

APCDs provide valuable information about risk that insurers can use to more accurately develop health insurance rates in a guaranteed issue market where insurers must accept all individuals, regardless of their health status and may not exclude pre-existing conditions. Many previously uninsured individuals will be entering the insurance market in 2014. The APCD will assist insurers because it provides them with more information about their own risk pool in relation to the rest of the health insurance market.

APCD information is valuable for mechanisms such as risk adjustment that will redistribute risk across all the insurers who are selling within certain market segments. Availability of market

data is critical for understanding the impact of risk adjustment on health insurance issuers. An insurer cannot know the financial impact of the risk adjustment mechanism on their own book of business without knowing how their average risk score compares to the state-wide average risk score. Without this knowledge, uncertainties will likely lead insurers to make conservative assumptions and implement higher premiums. Understating premiums threatens solvency and overstating premiums could result in reduced enrollment and large premium refunds as a result of the minimum loss ratio law.

Self-funded employer health plans, even though not participating in risk adjustment, will find this information useful for setting contribution rates and analyzing the predicted risk assumed for upcoming plan years. The APCD will make claims costs more transparent than ever before, revealing trends in medical costs, as well as the cost-effectiveness of certain medical treatments. This information will assist employer health plans in creating value-based designs for their health plans, thereby improving outcomes and reducing costs.

An APCD provides additional transparency for consumers, providing information about cost, as well as the effectiveness and safety of health care delivery provided by specific provider groups and hospitals. Consumers cannot assume responsibility for the cost and effectiveness of their health care without complete and accurate information.

Health care providers may use APCD information for setting competitive prices and to assist them in enforcing safe and effective outcomes across their work force. Many studies show that accountability and transparency greatly reduces medical error rates. Reducing medical errors saves lives and reduces costs.

Research conducted on data collected through APCDs may be used by states to develop an essential health benefits package that better meets the needs of its citizens by providing the most cost-effective health care. In addition, APCDs may utilize an IT infrastructure that can be integrated with health information exchange systems, thereby streamlining data collection and increasing its value.

GOVERNANCE:

The council collected information about government structures being used by other states for their APCDs. The council then adopted a “Mission and Principles” document in which they agreed that the governance structure should be as follows:

“The database should be administered by a quasi-governmental agency, which would be responsible for setting database guidelines, overseeing the development and implementation of the database, publishing reports, and providing the administration of the database, and setting security policies regarding access and use of the data.”

The council agreed that the quasi-governmental entity should be administratively attached to a state agency. The Commissioner of Securities and Insurance (CSI) would enforce any possible penalties on insurance companies for failing to report data. Also, any required administrative oversight of the APCD should be delegated to the CSI. The APCD quasi-government entity would be attached to CSI because the primary data reporting in the first years would be from payers (insurers and third party administrators), but there would be a provision which assigns DPHHS the task of enforcing provider reporting, as that will be required in the future.

PROVIDER REPORTING:

Mandatory reporting on clinical and claims data by providers should be required, just as it is for payers. Within a reasonable time-frame, providers could be asked to report payment and/or write-off costs data for uninsured patients. Economists estimate a large increase, of approximately 10%, on premiums for the insured is caused by uncompensated care on the uninsured. By reporting on the uninsured, the APCD will be able to directly measure the impact of the uninsured on medical costs. This will be of great value to policy makers for understanding how the uninsured are cared for and how they affect overall costs.

In regards to clinical data; a common response to quality estimates based on claims data is that only clinical data can adequately measure quality. Claims data can determine, for example, if someone is being treated for high cholesterol from the diagnosis code on the medical claim, and the presence of a claim for cholesterol lowering medication. However, without the clinical data this approach cannot determine if the patient has achieved the desired results. For example, has the cholesterol level been successfully lowered to the recommended level.

The difficulty with clinical data reporting is that it is often in paper format. This is slowly being addressed with initiatives across the country to encourage computerization. We believe that clinical data reporting should be required, but that the requirement needs to be phased in over time. Providers who implement Electronic Medical Records (EMRs) now have significant incentives from the Center for Medicare and Medicaid Services (CMS). In a few years they will face significant penalties from CMS for failing to use an EMR system. An APCD could add to this by creating similar incentives.

SECURITY:

A critical component to the development of an APCD is the privacy and security of the data. The APCD would include data received from many different sources, including: health care providers, insurance companies, and third party administrators. Since this will represent the protected health and claims information of Montana consumers, data security and patient privacy laws and regulations are of paramount importance.

Covered entities (health insurance issuers, health care providers and health care clearinghouses) must comply with all aspects of the federal Health Information Portability and Accountability Act of 1996 (HIPAA), including the Standards for Privacy of Individually Identifiable Health Information, 45 CFR Parts 160 and 164, subparts A and E, (the "Privacy Standards"), the Security Standards for the Protection of Electronic Protected Health Information, 45 CFR Parts 160 and 164, subparts A and C, (the "Security Standards"). The APCD would probably be a "business associate" of many different covered entities and therefore would also have to comply with all aspects of HIPAA privacy. The Health Information Technology for Economic and Clinical Health Act, as incorporated in the American Recovery and Reinvestment Act of 2009 (the "HITECH Act") also applies.

HIPAA and HITECH set rules and standards for protected health information ("PHI") and electronic protected health information ("Electronic PHI"), which is information about health status, the provision of health care, or the payment for health care that can be linked to an individual. HIPAA creates administrative, physical, and technical safeguards around the data. HITECH addresses the privacy and security concerns associated with electronic transmission of health and claims information. It extends the privacy and security requirements to the business associates of entities treated as "covered entities" under HIPAA, and creates new breach

notification rules for instances where a breach of PHI or Electronic PHI has occurred. Finally, and critical to the implementation of an APCD, it extends current accounting and disclosure requirements to information that is used to carry out treatment, and to payment and health care operations when an organization is using an electronic health record.

The governing entity must ensure that all data is at all times transmitted and stored in a secure and encrypted manner. As further protection, any data intake and storage management system must be able to manage intake and processing without manual intervention. When the data is used to create reports, certain information about a patient or member in a dataset will be replaced with a unique identifier. HIPAA rules offer further guidance when reports based on APCD analysis are ready for publication. These rules guide researchers and report developers about what can and cannot be shown when the number of patients or members in a particular category falls below an established floor or minimum cell size.

In Montana, the right to individual privacy is constitutionally protected under Article 2, Section 10 of the Montana Constitution. The Montana Legislature recognized that health care information is personal and sensitive information that if improperly disclosed or released, could do significant harm to the individual and as a result, enacted the Uniform Health Care Information Act, which is codified in Title 50, Chapter 16, Part 5 of the Montana Code Annotated. There are also Montana Administrative rules adopted under the authority of the Title 50 that apply to the protection of PHI as well.

This Act ensures that those health care providers that may not be subject to the federal HIPAA privacy and security laws, must comply with certain protections for the use and disclosure of the confidential health information of individuals. Additionally, the Insurance Information and Privacy Protection Act, which is codified in Title 33, Chapter 19 of the Montana Code Annotated applies to insurers, insurance producers and insurance support organizations, and establishes standards for the collection, use and disclosure of information gathered during the course of insurance transactions involving the confidential and sensitive medical claims information of individuals. In addition, there are Administrative Rules of Montana supporting that chapter: ARM 6.6.6901, et. seq., “Insurance Information and Privacy Protection and ARM 6.6.7001, et. seq., “Insurance Standards for Safeguarding Personal Information.”

To the extent that either the Uniform Health Care Information Act or the Insurance Information and Privacy Protection Act provide privacy and security protection beyond that required by HIPAA and HITECH, governing entity must ensure that those additional protections are provided. Additionally, Montana recognizes the individual's right privacy with respect to the collection of confidential personal information pertaining to that individual, and requires disclosure of any discovered breach of the security of a data system (Title 30, Chapter 14, Part 17 of the Mont. Code Ann.).

In addition, all corporations and business entities have a right to protection of their trade secrets pursuant to Title 30, Chapter 14, Part 4. The governing entity must also ensure that the APCD is managed within the constraints of all applicable rules regarding trade secrets for those organizations submitting data to the APCD.

The APCD will be either a hosted solution residing in a datacenter secured according to industry standards, or hosted in the governing entity's industry standards secured facility; either of which would be subject to safe harbor rules and be subject to HIPAA audits. To ensure the protection and security of PHI and Electronic PHI, the data center ultimately hosting the APCD should have characteristics similar to the following:

- Role-based database security framework, appropriately limiting access to APCD data and logging all activity based on user credentials.
- Encryption of data both in motion and at rest, incorporating HIPAA-compliant HTTPS, SSL, and NIST-approved hash algorithm.
- Firewall protection and intrusion prevention/detection, including logging of unauthorized access attempts.
- Daily backup of all data and datasets and storage of that data in encrypted form.
- Third-party data security audits.
- Secure data center facility characterized by 100% redundancy, secure/controlled access, and fault tolerance.
- Mandatory sign-in/-out and escorting of all visitors at all times.
- Data will be submitted to the data center using secure data transmission protocols.

When datasets are created for the purpose of developing reports both internally or externally through a formal data application or data request process, file formats, access, and transmission standards will be consistent with all required standards of HIPAA, HITECH, and Montana law.

An entity submitting data to the data center will have access to its own submitted PHI or Electronic PHI. Submitting entities will have access to the data submitted by other submitting entities only in de-identified format. The credentials (login and password) of the submitting and/or requesting entity will be used to determine the access level for each entity.

The governing entity administrative board will serve as the entity responsible for policy and the ongoing oversight of operations of the APCD, including any formal data application or data request process developed for reporting or research purposes.

COSTS AND FINANCES:

While health care cost databases can be useful tools in managing costs and quality, they do require investment. Costs include both one-time start up and implementation investments, and ongoing costs of database management, analytics, and reporting.

Some of the factors that affect the costs are the population covered, the number of payer sources, the number and types of data sources, the governance structure, security design, and analytics and reporting. Relatively speaking, Montana has low numbers in terms of population, payer sources, and the number and types of data sources, which could lower costs.

Additionally, as more health care cost databases have been developed across the country, there are more working models on which to start a Montana database, which will tend to mitigate costs. However, we proposed to include provider reporting of clinical data, which will add more data sources, and may increase the costs.

Start-up Costs - In a review of states with existing health care cost databases, we found the costs of developing and implementing those databases to average approximately \$1.1 million. In Colorado, the most recent state to develop a health care database, and one with a well thought out design, the cost was \$1.5 million. All of these databases capture administrative data, but have not added the clinical component we propose. Therefore, our start-up costs may be higher due to the addition of clinical data components. We anticipate the need for average

start up costs for the claims component - \$1.1 million, and up to an additional \$1.1 million to add the clinical components. However, the additional costs may prove to be far less than estimated if we can capitalize on existing data entities and platforms that already exist in Montana.

Ongoing Costs - Ongoing costs include those costs of administering the database, managing the data flow, providing the analytics, preparing reports, and providing governance to the effort. Ongoing costs in other states average about \$600K per year. Choices that affect the level of ongoing costs include governance structures, staffing levels, reporting choices, and analytical sophistication. We anticipate the need for the average level of ongoing costs for the Montana Health Care Database.

Funding Mechanisms - States use a variety of funding mechanisms for their health care cost databases. They include using general funds, assessments on payers and providers, Medicaid funds, private donations, federal, state and private grants, and sales of products and services. While sales of products and services may generate income over time, the advisory council believes that to guarantee ongoing funding, the Montana Health Care Database should seek funding from the Montana Legislature, and at the same time seek to reduce appropriated funds by seeking funding from state and private grant funds.

For the 2014-15 biennial, we anticipate the need for a biennial appropriation of approximately \$3.4 million for the implementation and operation of the database. Costs may be lower, however, depending on current vendor resources.

¹⁾ Clinical Performance Measures for Dental Care Plans” issued for Agency for Healthcare Research and Quality.

²⁾ Bradley, Herrin et al., 2006; Werner and Bradlow, 2006 –

(<http://www.esourceresearch.org/eSourceBook/AdministrativeDataSystems/1LearningObjectives/tabid/372/Default.aspx>).

³⁾ Final Report AHRQ Contract #233-02-0088, Task Order 13, Vol. 1, July 3, 2006

⁴⁾ <http://www.hcup-us.ahrq.gov/reports/clinical data.jsp>

⁵⁾ <http://www.hcup-us.ahrq.gov/datainnovations/clinicaldata/3MSummaryResultsReportFinal.jsp>.

⁶⁾ Shahian, Silverstein et al., 2006; Parker, Damberq et al., 2006; Austin and Tu, 2006

⁷⁾ <http://www.fhin.net/content/archive/#ui-tabs-4>

⁸⁾ U.S. Department of Health & Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics Data Brief No. 79, November 2011

⁹⁾ Rogers, 2009 AHRQ Publication No. 11-0026-EF, <http://www.ahrq.gov/research/iomqrdreport>

¹⁰⁾ High Level of Waste in Health Spending, Says Medicare and Medicaid Boss, <http://www.medicalnewstoday.com/articles/238654.php>, Reflections on Geographic Variations in U.S. Health Care http://www.dartmouthatlas.org/downloads/press/Skinner_Fisher_DA_05_10.pdf

Advisory Council Recommendations for the Montana Health Care Database

- The primary purpose of the Montana Health Care Data Base is to provide a rich source of data about our health care system, and to provide analytical capacity for stakeholders to better understand and improve that system regarding both quality and cost.
- The database will be most useful when it is populated by the most comprehensive set of health information available. Therefore, both payment data and clinical data will ultimately be captured.
- The data set for the database must be comprehensive, which is best achieved by a state mandate.
- Thresholds for the mandate should be set, both for payers and providers.
- The sources for the payment data should be as broad as possible, and should include commercial health insurance companies, pharmacy benefit managers, Medicaid, Healthy Montana Kids, third party administrators, the state employee health benefits system, Title 2 entities and claims clearinghouses.
- To the extent feasible, the database should include federal claims data from Montana, including data from Medicare, the federal employee health benefits system, the Indian Health Service, and Tricare.
- The sources for clinical data should include hospitals, provider groups, federally qualified health centers and rural health centers, individual providers, outpatient surgery centers, ASCs, freestanding labs and radiology centers, pharmacies and others.
- To the extent feasible, the clinical sources should also include the Veterans Administration, the Indian Health Service, and tribal and urban Indian health clinics.
- The database should develop methods for collecting data about the uninsured.
- The database should use national data collection standards, but should be flexible enough to include Montana specific standards where appropriate and reasonable.
- Recognizing that payers and providers are not all in the same stages of data capture, the database can and should be implemented in phases.
- The entities that provide data should have access to their own data, at a minimum; but access to information in the database must protect patient confidentiality and proprietary business information. Access to data must be limited to defined levels by type of entity.
- The data base should be administered by a quasi-governmental agency, which would be responsible for setting data base guidelines, overseeing the development and implementation of the database, publishing reports, and providing the administration of the database, and setting security policies regarding access and use of the data.

Technical Scope and Attributes Sub-Committee Recommendations for the Montana Health Care Database

- The system shall be developed and operated to fully protect the confidentiality of patient-identifiable information under the safeguards of legal standards, security protocols, access controls and access logging.
- Legislation should include a provision for stakeholder involvement to advise on data editing, and to ensure data quality, accuracy and reliability.
- The system should be developed and operated with considerations for minimizing the burden on data providers.
- Timeliness of data is an important consideration for identifying emerging patterns. Reporting frequency should balance this need with the workload requirement on submitters.
- The governing entity should seek historical data wherever available.
- Policies and procedures will be implemented to use, build and improve upon, and coordinate existing data sources and measurement efforts through the integration of data systems and standardization of concepts.
- In operating the system, the governing entity shall consider national standards where possible, but allow for additions as deemed necessary.
- Access to the entire dataset will be available in a de-identified format, subject to: protected patient confidentiality; proprietary business information rules; limits by defined levels by type of entity; and established policy. Each data provider will have full access to its own data. Analysis of the data by as many as possible should be encouraged, subject to confidentiality.
- At a minimum, the governing entity will provide a level of reporting and analysis for public consumption, following best practices for a consumer portal.

Claims Data – Additional Information

Medical Claims - Updates include the forthcoming and mandatory ICD-10-CM and ICD-10-PSC code sets, scheduled to be implemented in 2014. The differences between ICD-9 and ICD-10 are significant. The most obvious, however, is that ICD-10 codes document over 68,000 diagnoses, compared to only 14,000 ICD-9-CM codes.

The current system, International Classification of Diseases, 9th Edition, Clinical Modification (ICD-9-CM), does not provide the necessary detail for patients' medical conditions or the procedures and services performed on hospitalized patients. ICD-9-CM is 30 years old, has outdated and obsolete terminology, uses outdated codes that produce inaccurate and limited data, and is inconsistent with current medical practice. It cannot accurately describe the diagnoses and inpatient procedures of care delivered in the 21st century.

Pharmacy Claims - Two configurations of NDC exist, a ten and an eleven digit configuration. A majority of health care organizations and government agencies use the eleven digit code format. The first segment of the code identifies the labeler/manufacture code. The next segment, the product code, has information regarding drug strength, dosage form, and formulation. The last segment of the code, the package code, refers to package size and type.

These three segments yield information for any medication; including generic name or active ingredient, the manufacturer, the strength, route of administration, package size, and trade name. Providers of analytics software, including John Hopkins University, Verisk, OptumInsight, and NCQA have used NDC codes to derive meaningful clinical information related to cost, risk, quality, and outcomes measures.

Significant clinical value may also be added through the use of the Anatomical Therapeutic Chemical (ATC) codes adopted by the World Health Organization. In the ATC classification system, drugs are divided into categories based on the organ or system on which they act and their chemical, pharmacological and therapeutic properties. The availability of these codes can add significant clinical value to existing claims information. A more commonly used system of coding in the United States is the Generic Product Index (GPI), there are crosswalks available to link GPI and ATC codes.